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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/173,821	10/16/1998	PHILIP SPENCER RUDLAND	32040PCTUSA-	4674

7590 11/04/2002

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EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/04/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/173,821

Applicant(s)

RUDLAND ET AL.

Examiner

Sumesh Kaushal Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,9,13 and 15-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,9,13 and 15-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Applicant's response filed on 08/09/02 has been acknowledged.

Claims 4, 8, 14, and 30-32 are canceled.

Claims 1, 7, 9, 13, 17-18 and 25 are amended.

Claims 1, 7, 9, 13, 15-29 are pending and were examined in this office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

► *If the claims are amended, added and/or canceled in response to this office action the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED.*

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/09/02 has been entered.

Claim Rejections - 35 USC § 112

Claims 7, 13, 15-16 and 18-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification (***New Matter Situation***) in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The applicant fails to point out where in the specification there is support for the invention as claimed in recent amendment filed on 08/09/02. For example the applicant fails to point out where in the instant specification there is a description for a neuronal cell line obtained from a transgenic rat, a transgenic rat, and the method of producing the same wherein the transgenic rat (as claimed) encodes in their genome C-erb-B-2 or TGF α operatively linked to a human NF-L gene promoter.

Claims 1, 7, 9, 13, 15-29 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic rat encoding in their genome NS-LtsA58 δ t (*human NF-L gene promoter operatively linked to SV40tsA58*), does not reasonably provide enablement for a neuronal cell line obtained from a transgenic rat, a transgenic rat, and the method of producing the same, wherein the transgenic rat (as claimed) encodes in their genome C-erb-B-2 and TGF α operatively linked to a human NF-L gene promoter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention **commensurate in scope** with these claims, for the same reasons of record as set forth in the earlier official action mailed on the 02/11/02.

The applicant argues that in view of recent amendment that recites claim limitation "human NF-L gene promoter" in claims 7, 9, 13, 18 and 25 the instant rejection should be withdrawn (response, page 6, para. 1-2). However, this is not found persuasive because applicant's argument alone cannot take place of evidence lacking in the record (see *In re Scarbrough* 182 USPQ, (CCPA) 1979). The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)).

It is important to note that, the scope of the instant claims include rats encoding human NF-L gene promoter operably linked to SV40tsA58, C-erb-B-2 or TGF α . At best the instant specification is only enabled for a transgenic rat encoding in their genome NS-LtsA58 δ t containing SV40tsA58 operatively linked a human neurofilament gene promoter NF-L (spec. page 30, table-3). In addition the specification teaches the development and breeding of a neuronal cell line NF2C (ECACC Acc. No. 96092754) derived from a NF-Lts58U δ t transgenic

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rat (page 30 table-3, page 28, table-2). The specification further disclosed transgenic rats encoding MMTVLTR-TGF α and MMTVLTR-C-erb-B-2, which contain MMTV-LTR promoter but fails to disclose any transgenic rat whose genome contain human NF-L gene promoter operatively linked to TGF α or C-erb-B-2 (spec. page 50, table-6).

The state of transgenic art at the time of filing was such that phenotype of an animal is determined by a complex interaction of genetics and environment. The transgene expression and physiological consequences of transgene products are not always accurately predictable because cis elements are controlled differently by various transacting factors in the genome of an animal. Furthermore, the lack of understanding of essential genetic control elements make it difficult to predict the behavior of a transgene in any and all animals because the expression is influenced by position effect in transgenic animals. The individual gene of interest, promoter, enhancer, coding or non-coding sequences present in the transgene construct and the site of integration, are the important factors that govern the expression of a transgene (see Wall RJ Theriogenology 45:57-68, 1996, ref. of record).

Since the making transgenic rats wherein the human NF-L gene promoter is operatively linked to a conditional oncogene, transforming gene or immortalizing gene or cell cycle affecting gene like TGF α or C-erb-B-2 is not routine in the art experimentation left to those skilled in the art is unnecessarily, improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See Ex parte Singh, 17 USPQ2d 1714 (BPAI 1991).

In addition, claims 1, 9 and 17 stand rejected because instant claims fail to recite the required phenotype (*wherein the transgenic rat over express Large T-antigen in brain as compared to a non-transgenic rat*), which would guide one skill in the art how to use the claimed transgenic rat. Incorporation of the suggested phenotype in these claims would over come this rejection.

Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed. The undue experimentation required would include making and testing neuronal cell line obtained from a transgenic rat, a transgenic rat, and

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the method of producing the same wherein the transgenic rat encodes in their genome C-erb-B-2 and TGF α operatively linked to a human NF-L gene promoter.

Conclusion

Claims 1, 7, 9, 13, 15-29 are rejected.

A neuronal cell line obtained from a transgenic rat and a transgenic rat, which encode in its genome a transgene comprising NS-LtsA58 δ t (*human NF-L gene promoter operatively linked to SV40 tsA58*) is free of prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is (703) 305-6838. The examiner can normally be reached on Monday-Friday from 9:00 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Irem Yucel Ph.D. can be reached on (703) 305-1998. The fax-phone number for the organization where this application or proceeding is assigned as (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Zeta Adams, whose telephone number is (703) 305-3291.

S. Kaushal
PATENT EXAMINER

Scott D. Priebe
SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER